

Fact Sheet for Pregnant Women: Understanding Results from the Trioplex Real-Time RT-PCR Assay (Trioplex rRT-PCR)

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Dear Madam:

You are being given this Fact Sheet because your blood, urine, cerebrospinal fluid (CSF) or amniotic fluid was tested for evidence of Zika virus infection. This testing is being done because you have symptoms of Zika virus infection and either you live in or have traveled to areas with ongoing Zika virus transmission, or you have a male sex partner who has lived in or traveled to an area with ongoing Zika virus transmission. The test being used on your specimen(s) is called the Trioplex Real-Time RT-PCR Assay (Trioplex rRT-PCR), which is a laboratory test designed to help detect Zika virus infection in humans. This test can also detect dengue virus and chikungunya virus, which are also transmitted by mosquito bites, and infections with these viruses are seen in many of the same places and share similar symptoms as Zika virus infections.

This Fact Sheet contains information to help you understand the risks and benefits of using the Trioplex rRT-PCR. You may want to discuss with your health care provider the benefits and risks described in this Fact Sheet.

What is Zika virus Infection?

Zika virus infection is caused by the Zika virus and is most often spread to people through mosquito bites. A woman infected with Zika virus during pregnancy can pass the virus to her fetus. Zika virus can be sexually transmitted by a man to his sex partners. Since 2015, a large number of Zika virus cases have been reported in many South and Central American countries.

Most people who are infected with Zika virus do not have any symptoms. Those that do usually have mild illness with symptoms that may include fever, joint pains, rash, or redness of the eyes. These symptoms often resolve on their own within a week.

There have been reports from Brazil of birth defects and other poor pregnancy outcomes in pregnant women with Zika virus infection. The connection between Zika virus infection and pregnancy problems is not well understood. Zika virus infection in a mother does not definitely mean she will have pregnancy problems. A woman who is infected with Zika during pregnancy may have an increased risk of miscarriage, a baby that is stillborn, or a baby that is small at birth, has incomplete brain development, and/or eye problems. Women who get Zika virus while pregnant should be monitored more closely throughout their pregnancy. There have also been reports of a possible link between Zika virus infection and an illness that can cause temporary paralysis (Guillain-Barré syndrome).

What is the Trioplex rRT-PCR?

The Trioplex rRT-PCR is a laboratory test designed to detect Zika virus and two other viruses, also spread by mosquito bites, which can cause similar symptoms to Zika virus infection: dengue virus and chikungunya virus. The Food and Drug Administration (FDA) has

not cleared or approved this test. No FDA-cleared or approved tests exist that can tell whether you have Zika virus infection or can distinguish or differentiate between Zika virus, dengue virus and chikungunya virus infections. However, FDA has authorized the use of this test under an Emergency Use Authorization (EUA).

Why is my sample being tested using the Trioplex rRT-PCR?

You are being tested because you have symptoms that resemble Zika virus infection and because you either live in or have traveled to places with ongoing Zika virus transmission or have had sex with a male sex partner who has lived in or traveled to an area with ongoing Zika virus transmission. The sample(s) collected from you will be tested using the Trioplex rRT-PCR to help find out whether you may be infected with Zika virus or if the cause of your illness is dengue virus or chikungunya virus. The test results, along with other information, could help your doctors make decisions about how to take care of you and better monitor your pregnancy.

What are the known and potential risks and benefits of the Trioplex rRT-PCR?

You may feel discomfort when the sample is taken. There is a very small chance that the test result is incorrect (see next paragraphs for more information). The results of this test, along with other information, can help your health care provider make decisions about how to take care of you and your baby.

If this test is positive for Zika virus, does it mean that I have Zika virus infection?

If you have a positive test, it is very likely that you have or have had a Zika virus infection. There is a very small chance that this test can give a positive result that is wrong; this is called a false positive result. If your result from this test is positive, your health care provider or health department will work with you to help you understand the steps you should take to care for yourself. They will also work closely with you to monitor the health and development of your child.

If this test is positive for Zika virus, does it mean that my child will have a birth defect?

No, not necessarily. The link between Zika virus infection and pregnancy problems such as birth defects, is not well understood. While this test result may lead your doctors to follow your pregnancy more closely, a Zika virus infection in a mother does not always mean the child will be harmed.

If this test is positive for dengue or chikungunya viruses, does it mean that I have dengue virus infection or chikungunya virus infection?

If you have a positive test for dengue virus or chikungunya virus, it is very likely you have a dengue virus infection or chikungunya virus infection. There is a very small chance that this test can give a positive result that is wrong (a false positive result). If your result from this test is positive, your health care provider or health department will work with you to help you understand the steps you should take to care for yourself.

If this test is negative for Zika virus (or dengue virus or chikungunya virus), does it mean that I do not have Zika virus infection (or dengue virus infection or chikungunya virus infection)?

A negative test for Trioplex rRT-PCR means that virus was not found in your sample. For Zika virus, a negative result for a sample collected less than a week after the start of illness usually means that Zika virus did not cause your recent illness. Likewise, negative dengue or chikungunya results usually indicate that these viruses did not cause your recent illness.

It is possible for this test to give a negative result that is incorrect (false negative) in some people with a Zika virus infection. Most people with Zika virus infection have virus in their blood for up to a week following the start of illness. A negative result that is incorrect can happen if your body fights a Zika virus infection faster than most other people do. It can also happen if your illness/symptoms started earlier than the date you first noticed them. In these cases, the virus may already be gone from your body before the sample is taken for testing.

If your Zika result for the Trioplex rRT-PCR is negative, you should ask your health care provider or health department if additional testing may be needed. It is important that you work with your health care provider or health department to help you understand the next steps you should take. Your health care provider will work with you to continue to monitor your health and the health of your baby.

What is an Emergency Use Authorization (EUA)?

An EUA is a tool that FDA can use to allow the use of certain medical products for certain emergencies based on scientific data. The U.S. Secretary of Health and Human Services (HHS) has declared that circumstances exist to allow the emergency use of authorized diagnostic tests for Zika virus infection, such as the Trioplex rRT-PCR.

At this time, there are no FDA approved/cleared alternative tests available that detect Zika virus. FDA has authorized the emergency use of the Trioplex rRT-PCR to test for the presence of Zika virus in blood, CSF, amniotic fluid and urine specimens and for differentiation of Zika virus infections from dengue virus and chikungunya virus infections using serum and CSF. Use of this test is authorized only for the duration of the threat of the emergency, unless it is terminated or revoked by FDA sooner.

How can I learn more?

Information about Zika virus and any significant new findings observed during the course of the emergency use of the Trioplex rRT-PCR will be made available at the CDC website: <http://www.cdc.gov/zika/index.html>.

Please also contact your health care provider if you have any questions.